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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/801,381	Applicant(s) FIGUEROA ET AL.	
	Examiner Jennifer K. Michener	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
 4a) Of the above claim(s) 11-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/28/05:3/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a method of coating, classified in class 427, subclass 2.21.
 - II. Claims 11-20, drawn to a bioactive dosage, classified in class 428, subclass 402.2+.
 - III. Claims 21-28, drawn to a bioactive agent application system, classified in class 118, subclass 313.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used in printing dots on paper or the product can be made by masking the substrate and dip-coating to form the dots.
3. Inventions III and II are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed

can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product as claimed may be formed by a different apparatus such as a dip coating apparatus.

4. Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to apply a non-bioactive agent.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for each of the Groups is not required for the others, restriction for examination purposes as indicated is proper.

8. During a telephone conversation with Bradley Haymond on 2/17/2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Voss et al. (4,322,449), as cited by Applicant.

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern (abstract; throughout; col. 5, lines 35-37).

Voss teaches the control of various parameters, such as dots/second, volume/drop, number of ejection strokes, etc. As is known in the art and as taught in the specification, controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control.

Voss teaches the use of a piezoelectric ejection element (abstract) with a number of nozzles (col. 4, line 18).

Voss provides the bioactive agent in a solvent (col. 5, lines 52-62), that inherently dries by evaporation, with precisely controlled concentration and drop volume (col. 6, line 5).

Voss refers to some dots as being discrete, with a specified volume. Dots are "spaced".

Voss also uses his method to write letters (Ex. 2), requiring, in some instances, at least a partial overlap of dots.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss.

Voss teaches that which is disclosed above, but fails to specifically teach the standard deviation regarding the spacing or overlapping of droplets. However, Voss goes to great lengths to discuss the precision, uniformity, and reproducibility of the dot sizes, dosages, and concentrations he applies. Because a plate of nozzles may be used in a fixed arrangement, the dots formed should always be spaced the same. It would have been obvious to an ordinary artisan wishing to achieve uniformity and precision in dosing to select and maintain a spacing that is consistent from dot to dot, i.e., with a standard deviation of less than 15%.

It is well settled that determination of optimum values of cause effective variables such as standard deviation is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

16. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, as applied above, in view of Voges (5,894,841).

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Voss teaches that which is disclosed above, namely forming droplets of bioactive agent using piezoelectric ejection elements. What Voss does not teach is the use of thermal ejection elements.

It is Examiner's position that these two species of inkjet printing are obvious variants that would have been known to an ordinary artisan and cites Voges for teaching the same.

Voges teaches a method of forming droplets of bioactive agent by using one of the two forms of inkjet printing, namely either a piezoelectric ejection device or a thermal ejection device.

Since Voss teaches printing precise drops of bioactive agent using a piezoelectric element, such as is used in inkjet printing, and Voges teaches that either the piezoelectric or thermal types of inkjet printing are suitable for forming precise droplets of bioactive agent, Voges would have reasonably suggested the use of a thermal element in the method of Voss. It would have been obvious to one of ordinary skill in the art to use the interchangeability teachings of Voges in the method of Voss to provide Voss with a suitable, successful alternative element for dosing dots in a precise manner. Like Voss, Voges teaches a plurality of nozzles or ejection orifices that provide uniformly-sized droplets.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571)

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272-1424. The examiner can normally be reached on Mondays & on Tuesday and Wednesday afternoons.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Michener
Primary Examiner
Art Unit 1762
September 19, 2005